



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAY 10 1999

1767 '99 Re: Lumbar I/F Cage®  
Docket No. 99E-1115

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
U.S. Patent and Trademark Office  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,834,757 filed by DePuy AcroMed, Inc. under 35 U.S.C. § 156. The medical device claimed by the patent is Lumbar I/F Cage®, which was assigned premarket approval application (PMA) No. P960025.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on February 2, 1999, which makes the submission of the patent term extension application on April 2, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: William R. Coffey  
Barnes & Thornburg  
11 S. Meridian St  
Indianapolis, IN 46204

99E-1115

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**Memorandum**

Date: **MAY 10 1999**

From: **Brian J. Malkin, Associate Director for Patents and Hearings**  
**Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application**  
**for Lumbar I/F Cage<sup>®</sup>**

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned medical device under the Docket Number **99E-1115** stating that this particular patent is eligible for regulatory review.. The Patent Number is **4,834,757**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.